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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,557	03/31/2004	Diane Bihary		7432

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INDIANAPOLIS, IN 46204

EXAMINER	
SCHAPER, MICHAEL T	

ART UNIT	PAPER NUMBER
3775	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/814,557	BIHARY ET AL.	
	Examiner	Art Unit	
	MICHAEL T. SCHAPER	3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 November 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 20-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,20-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

In view of the appeal brief filed on 16 November 2009, PROSECUTION IS HEREBY REOPENED. New grounds of rejection set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 6, the limitation "**wherein the sealable valve is a stop check valve**" renders the claim indefinite because it lacks antecedent basis, and it appears that the claim language meant to read "wherein the stop check valve is a sealable valve".

As to claim 28, the limitation "**a second o-ring located within the first groove**" renders the claim indefinite because the first groove is also occupied by the first o-ring, and it appears that the claim language meant to read "a second o-ring located within the second groove".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 20, 22, and 25-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Parry et al. (US 2005/0149043).

Parry discloses a kit providing a handheld instrument (8) for insertion of an acetabular liner into an acetabular cup comprising a shaft (12) having an internal

channel (54) therethrough and a first (proximal end) and a second (distal end) end portion, the first end portion capable of sealingly engaging with a bulb syringe or with a hand held vacuum producing device; and a head portion (100) having a curvilinear outer perimeter configured to sealingly engage the inner surface of an acetabular liner and configured to abut a 360 degree portion of the inner surface of an acetabular liner and operably attached to the second end portion of the shaft and having an inner channel (at 112) therethrough operably connected to the internal channel of the shaft; the head portion further comprising a first o-ring (111) circumscribing the curvilinear outer perimeter of the head portion and sized to sealingly fit between the curvilinear outer perimeter of the head portion and an acetabular liner; the head portion further comprising a second o-ring (other 111) circumscribing the curvilinear outer perimeter of the head portion and adjacent the first o-ring, a secondary inner channel (at 118,114) having a first and a second end portion and operably connected at the first end portion to the internal channel and opening at the second end portion at the outer perimeter of the head portion between the first and second o-ring; wherein the shaft is bent between the first end portion and the second end portion at *about* 30 degrees (see FIG. 2, as to claims 8-10); wherein the head portion comprises an internal chamber (108) communicating with the inner channel, and wherein the second end portion of the shaft sealingly fits within the internal chamber; and a plurality of heads, each head having a curvilinear outer perimeter and configured to be operably attached to the second end portion of the shaft such that an inner channel of the head connects to the internal channel of the shaft, each of the plurality of heads having a curvilinear outer perimeter

sized to at least partially fit within an acetabular liner (¶11, 35, 92); wherein each of the plurality of heads has an outer perimeter of a size different than the size of each of the other plurality of heads (¶11, 35, 92); wherein the plurality of heads comprises a first head having a curvilinear outer perimeter sized to at least partially fit within a first acetabular liner having a first diameter; and a second head having a curvilinear outer perimeter sized to at least partially fit within a second acetabular liner having a second diameter, the first diameter different from the second diameter (¶11, 35, 92); wherein the head is configured to sealingly fit within an acetabular liner (see abstract); the head comprising a first groove (see FIG. 6) circumscribing the curvilinear outer perimeter of the head; and a first o-ring (111) located within the first groove and sized to sealingly fit between the curvilinear outer perimeter of the head and an acetabular liner; the head further comprising a second groove (see FIG. 6) circumscribing the curvilinear outer perimeter of the head and adjacent the first groove; a second o-ring (other 111) located within the first groove; and a secondary inner channel (114, 118) having a first and a second end portion and operably connected at the first end portion to the internal channel and opening at the second end portion at the outer perimeter of the head between the first and second groove (see FIG. 6).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-11, 20-22, and 25-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parry et al. (US 2005/0149043) in view of Amstutz (US 3859992) further in view of Leach (US 4050311).

Parry discloses a kit providing a handheld instrument (8) for insertion of an acetabular liner into an acetabular cup comprising a shaft (12) having an internal channel (54) therethrough and a first (proximal end) and a second (distal end) end portion, the first end portion capable of sealingly engaging with a bulb syringe or with a hand held vacuum producing device; and a head portion (100) having a curvilinear outer perimeter configured to sealingly engage the inner surface of an acetabular liner and configured to abut a 360 degree portion of the inner surface of an acetabular liner and operably attached to the second end portion of the shaft and having an inner channel (at 112) therethrough operably connected to the internal channel of the shaft; the head portion further comprising a first o-ring (111) circumscribing the curvilinear outer perimeter of the head portion and sized to sealingly fit between the curvilinear outer perimeter of the head portion and an acetabular liner; the head portion further comprising a second o-ring (other 111) circumscribing the curvilinear outer perimeter of the head portion and adjacent the first o-ring, a secondary inner channel (at 118,114) having a first and a second end portion and operably connected at the first end portion to the internal channel and opening at the second end portion at the outer perimeter of the head portion between the first and second o-ring; wherein the shaft is bent between the first end portion and the second end portion at *about* 30 degrees (see FIG. 2, as to

claims 8-10); wherein the head portion comprises an internal chamber (108) communicating with the inner channel, and wherein the second end portion of the shaft sealingly fits within the internal chamber; and a plurality of heads, each head having a curvilinear outer perimeter and configured to be operably attached to the second end portion of the shaft such that an inner channel of the head connects to the internal channel of the shaft, each of the plurality of heads having a curvilinear outer perimeter sized to at least partially fit within an acetabular liner (¶11, 35, 92); wherein each of the plurality of heads has an outer perimeter of a size different than the size of each of the other plurality of heads (¶11, 35, 92); wherein the plurality of heads comprises a first head having a curvilinear outer perimeter sized to at least partially fit within a first acetabular liner having a first diameter; and a second head having a curvilinear outer perimeter sized to at least partially fit within a second acetabular liner having a second diameter, the first diameter different from the second diameter (¶11, 35, 92); wherein the head is configured to sealingly fit within an acetabular liner (see abstract); the head comprising a first groove (see FIG. 6) circumscribing the curvilinear outer perimeter of the head; and a first o-ring (111) located within the first groove and sized to sealingly fit between the curvilinear outer perimeter of the head and an acetabular liner; the head further comprising a second groove (see FIG. 6) circumscribing the curvilinear outer perimeter of the head and adjacent the first groove; a second o-ring (other 111) located within the first groove; and a secondary inner channel (114, 118) having a first and a second end portion and operably connected at the first end portion to the internal

channel and opening at the second end portion at the outer perimeter of the head between the first and second groove (see FIG. 6).

Parry discloses the claimed invention except for a bulb syringe sealingly engaged with the first end portion of the shaft and operably connected to the internal channel of the shaft; wherein the hand held vacuum producing device is a bulb syringe; further comprising a valve, the valve operable to seal the internal channel such that air is not allowed to pass between the atmosphere and the internal channel through the valve; further comprising a stop check valve having an inlet and an outlet, the inlet operably connected to the internal channel and the outlet operably connected to the atmosphere, such that when the stop check valve is in a non-stopped position, air from the atmosphere is not allowed to pass into the internal channel through the stop check valve but air from the internal channel is allowed to pass to the atmosphere through the stop check valve and such that when the stop check valve is in a stopped position, air from the internal channel is not allowed to pass into the atmosphere through the stop check valve; and a valve movable between a first position and a second position and having an inlet and an outlet, the inlet operably connected to the atmosphere and the outlet operably connected to the bulb syringe, such that when the valve is in the first position, air is not allowed to pass between atmosphere and the internal channel, and when the valve is in the second position, air is allowed to pass between the atmosphere and the internal channel; wherein the stop check valve is a sealable valve; wherein the stop check valve is located on the bulb syringe, such that air passing between the inner

channel and the atmosphere through the stop check valve passes through the bulb syringe.

Amstutz discloses a hand held vacuum (see abstract, FIGS. 1-2) sealingly engaged with the first end portion of the shaft and operably connected to the internal channel of the shaft; further comprising a valve (at 34—for claim 4), the valve capable of sealing the internal channel such that air is not allowed to pass between the atmosphere and the internal channel through the valve; and a valve (at 34—for claim 5) movable between a first (closed 46) position and a second (opened 46) position (toggling 46) and having an inlet and an outlet, the inlet operably connected to the atmosphere and the outlet operably connected to the hand held vacuum, such that when the valve is in the first position, air is not allowed to pass between atmosphere and the internal channel, and when the valve is in the second position, air is allowed to pass between the atmosphere and the internal channel (see FIG. 2) for controlling the vacuum properties inside of the shaft for placement of cup into the site (see Abstract).

Leach discloses a hand held vacuum producing device being a bulb syringe (18, see FIG. 3); further comprising a stop check valve (ref. no. 16, see col. 2 / line 58 – col. 3 / line 22) having an inlet and an outlet, the inlet operably connected to the internal channel and the outlet operably connected to the atmosphere, such that when the stop check valve is in a non-stopped position (34 depressed, or "released"), air from the atmosphere is not allowed to pass into the internal channel through the stop check valve but air from the internal channel is allowed to pass to the atmosphere through the stop check valve and such that when the stop check valve is in a stopped position (34

not depressed, or not "released"), air from the internal channel is not allowed to pass into the atmosphere through the stop check valve; wherein the stop check valve is a sealable valve; wherein the stop check valve is located on the bulb syringe (see FIG. 1), such that air passing between the inner channel and the atmosphere through the stop check valve passes through the bulb syringe (see FIGS. 1-3) for the obvious reason of an easy and less complicated manners of vacuum production.

At the time of invention, it would have been obvious to one of ordinary skill in the art to have modified the device of Parry with a hand held vacuum sealingly engaged with the first end portion of the shaft and operably connected to the internal channel of the shaft; further comprising a valve, the valve capable of sealing the internal channel such that air is not allowed to pass between the atmosphere and the internal channel through the valve; and a valve movable between a first position and a second position and having an inlet and an outlet, the inlet operably connected to the atmosphere and the outlet operably connected to the hand held vacuum, such that when the valve is in the first position, air is not allowed to pass between atmosphere and the internal channel, and when the valve is in the second position, air is allowed to pass between the atmosphere and the internal channel in view of Amstutz for controlling the vacuum properties inside of the shaft for placement of cup into the site and furthermore a hand held vacuum producing device being a bulb syringe; further comprising a stop check valve having an inlet and an outlet, the inlet operably connected to the internal channel and the outlet operably connected to the atmosphere, such that when the stop check valve is in a non-stopped position, air from the atmosphere is not allowed to pass into

the internal channel through the stop check valve but air from the internal channel is allowed to pass to the atmosphere through the stop check valve and such that when the stop check valve is in a stopped position, air from the internal channel is not allowed to pass into the atmosphere through the stop check valve; wherein the stop check valve is a sealable valve; wherein the stop check valve is located on the bulb syringe, such that air passing between the inner channel and the atmosphere through the stop check valve passes through the bulb syringe in view of Leach for the obvious reason of an easy and less complicated manners of vacuum production.

Claims 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parry et al. (US 2005/0149043) in view of Amstutz (US 3859992) further in view of Leach (US 4050311).

Parry, Amstutz, and Leach disclose the claimed invention except for the device being characterized wherein the plurality of heads comprises a first head, a second head and a third head, the first head having a curvilinear outer perimeter sized to at least partially fit within a 26 mm diameter acetabular liner, the second head having a curvilinear outer perimeter sized to at least partially fit within a 28 mm diameter acetabular liner, and the third head having a curvilinear outer perimeter sized to at least partially fit within a 32 mm diameter acetabular liner; and wherein the first acetabular liner and the second acetabular liner have diameters of 26 mm, 28 mm, 32 mm, 36 mm or 38 mm.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the device as such, since that discovering an optimum value of a result effective variable involves only routine skill in the art, and it is well known in the art to have at least 3 different heads available to times of surgery as well as these sizes as they are common sizes.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL T. SCHAPER whose telephone number is (571)270-7413. The examiner can normally be reached on M-F, 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached on (571)272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. T. S./
Examiner, Art Unit 3775

/Thomas C. Barrett/
Supervisory Patent Examiner, Art Unit 3775